

Application No. 08/203,004

Amendment dated November 13, 2007

Amendment and Response to Office action dated May 11, 2007

Remarks/Arguments:

This Amendment and Response is fully responsive to the non-final Office Action dated May 11, 2007.

Claims 43, 44, 47, 49-62, 64-72, and 74-77 are currently pending in this application and currently stand rejected. By this present amendment, claims 43, 44, 49-62, 64-66, 69, 71, and 76 are canceled and claims 47, 70, 75, and 77 are amended. Claims 67, 68, 72, and 74 were previously presented. No new matter has been added.

Claims 43, 44, 47, 49-62, 64-72, and 74-77 stand rejected under 35 U.S.C. 112, first paragraph, on the new grounds that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to practice the invention commensurate in scope with these claims. *See Office Action, section 7.* In particular, the Examiner contends that these claims are drawn to a method of treating a malignant tumor comprising any type of tumor cell, which is not enabled by the specification. Claims 43, 44, 49-62, 64-66, 69, 71, and 76 have been canceled without prejudice and the rejection of these claims is now moot. Regarding remaining claims 47, 67, 68, 70, 72, 74, 75, and 77, it is explicitly noted in the Office Action that the specification is enabling for a composition and method of treating a malignant tumor wherein the malignant tumor is melanoma, colon cancer, lung cancer or kidney cancer. *See Office Action, p. 7, first paragraph.* It is further noted in the Office Action that the specification teaches that the cancers treatable with the present invention include melanoma, breast, lung, colon, kidney, and prostate. *See Office Action, p. 7, third paragraph.* Applicant has amended independent claim 47 to recite the limitation, “wherein said malignant tumor is from a cancer selected from the group consisting of melanoma cancer, lung cancer, colon cancer, breast cancer, kidney cancer, and prostate cancer.” Support for this amendment can be found at least on p. 11, lines 19-25 of the written description. This amendment is made solely to expedite prosecution, without any admission as to the propriety of the enablement rejection, and without prejudice to Applicant’s rights to pursue the claim as originally written in a future application. Applicant respectfully requests the rejection be withdrawn.

Claims 47, 65-72, 74, 75, and 77 stand rejected under 35 U.S.C. 112, first paragraph, on the new grounds that the specification does not contain a written description of the claimed invention because the Examiner contends that the limitation of “repeating said administration at least six times

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at spaced apart intervals" in independent claim 47 has no clear support in the specification and the claims as originally filed. *See Office Action, section 8.* Solely to expedite prosecution, and without any admission as to the propriety of the rejection, independent claim 47 has been amended to remove the phrase, "at spaced apart intervals," and to now recite, "repeating said administration of said composition for a total of at least six administrations of said composition". Support for this limitation can at least be found in Examples 4, 5, and 6 of the specification. *See p. 27, lines 22-28, p. 31, line 22 to p. 32, line 11, and p. 41, lines 22-24 of the written description.* Applicant respectfully requests this rejection be withdrawn.

Claims 47, 65-72, 74, 75, and 77 also stand rejected under 35 U.S.C. 112, first paragraph, on the new grounds that the specification does not contain a written description of the claimed invention because the Examiner contends that the limitation of "wherein said composition elicits at least one of the following upon administration... an inflammatory immune response... a delayed-type hypersensitivity response... activated T lymphocytes that infiltrate the tumor..." in independent claim 47 has no clear support in the specification and the claims as originally filed. *See Office Action, section 9.* Solely to expedite prosecution, and without any admission as to the propriety of the rejection, independent claim 47 has been amended to remove this recitation. Accordingly, this rejection is now moot.

Claims 76 and 77 stand rejected under 35 U.S.C. 112, first paragraph, on the new grounds that the specification does not contain a written description of the claimed invention because the Examiner contends that the limitation of "predominantly CD8 + CD4" in these claims has no clear support in the specification and the claims as originally filed. *See Office Action, section 10.* Claims 76 and 77 also stand rejected under 35 U.S.C. 112, second paragraph, on the new grounds that they fail to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the Examiner contends that the terms "predominantly" and "CD8 + CD4" render the claims indefinite. *See Office Action, section 11.* Claim 76 has been canceled without prejudice. Claim 77 has been amended to remove the recitation of "said lymphocytes being predominantly CD8 + CD4". Accordingly, this rejection is now moot.

Claims 43, 44, 49-62, and 64 stand rejected under 35 U.S.C. 103(a) for the reasons set forth previously in the paper mailed November 29, 2000, Section 7, pages 5-6. *See Office Action, section 5.* Claims 43, 44, 49-62, and 64 also stand rejected under 35 U.S.C. 103(a) on the new grounds of

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being unpatentable over U.S. Patent No. 5,484,596, in view of Berd et al, 1989 and Geczy et al. *See* Office Action, section 16. Solely to expedite prosecution, claims 43, 44, 49-62, and 64 have been canceled without prejudice to Applicant's rights to pursue these claims in a future application and without any admission as to the propriety of the rejections. Accordingly, these rejections are now moot.

Claims 47, 65-72, 74, and 75 stand rejected under 35 U.S.C. 103(a) on the new grounds of being unpatentable over U.S. Patent No. 5,484,596 in view of Berd et al, 1989, U.S. Patent No. 5,651,993, Riott et al., U.S. Patent No. 5,008,183, and Geczy et al. *See* Office Action, section 17. Claims 65, 66, 69, and 71 have been canceled without prejudice and the rejection of these claims is now moot. Regarding remaining claims 47, 67, 68, 70, 72, 74, and 75, independent claim 47 has been amended to recite, "repeating said administration of said composition for a total of at least six administrations of said composition; and administering a therapeutically effective amount of cyclophosphamide to the patient only prior to the first administration of said composition."

Dependent claim 70 has been amended to recite, "wherein administering a therapeutically effective amount of cyclophosphamide comprises administering a dose of about 300 mg/M² of cyclophosphamide prior to the first administration of said composition." These amendments have been made solely to expedite prosecution without any admission as to the propriety of the rejections, and support for these amendments can at least be found in Examples 4, 5, and 6 of the specification. *See* p. 27, lines 22-28, p. 32, line 22 to p. 33, line 2, and p. 41, lines 22-24 of the written description. Minor changes have also been made to claims 47, 75, and 77 to reflect proper antecedent basis.

None of the references relied upon, either alone or in combination, disclose, teach, or suggest a method of treating a malignant tumor including the steps of administering a composition comprising hapten-conjugated autologous tumor cells, repeating the administration of the composition for a total of at least six administrations of the composition, and administering a therapeutically effective amount of cyclophosphamide only prior to the first administration of the composition as required by the claims. Accordingly, Applicant respectfully submit that for at least the foregoing reason, claim 47 is allowable as written over the cited references, and that claims 67, 68, 70, 72, 74, and 75 are allowable over the cited references as depending from an allowable claim.

Claims 47, 65-71, and 74 stand rejected on the new ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3-10 of U.S. Patent No. 6,458,369.

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Applicant defers filing a Terminal Disclaimer directed to U.S. Patent No. 6,458,369 until one or more of the presently rejected claims is considered allowable by the Examiner. Accordingly, Applicant respectfully request this rejection be withdrawn.

Claims 44, 58, 59, and 64 stand rejected on the new ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,333,028. Claims 44, 58, 59, and 64 have been canceled without prejudice. Accordingly, this rejection is now moot.

The Applicant respectfully request that a timely Notice of Allowance be issued in this case. Should the Examiner wish to discuss any aspect of this application, the Applicant's attorney suggests a telephonic interview to expedite issuance of a patent.

Respectfully submitted,

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Date

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